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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation

Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

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FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at:

https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2479

This is to notify the public that the EPC Program would find the following information on *Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is

a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question (KQ) 1

What are the benefits and harms of nonpharmacological treatments of UI in women, and how do they compare with each other?

I. How do nonpharmacological treatments affect UI, UI severity and frequency, and quality of life when compared with no active treatment?
II. What are the harms from nonpharmacological treatments when compared with no active treatment?
III. What is the comparative effectiveness of nonpharmacological treatments when compared with each other?
IV. What are the comparative harms from nonpharmacological treatments when compared with each other?
V. Which patient characteristics, including age, type of UI, severity of UI, baseline diseases that affect UI, adherence to treatment recommendations, and comorbidities, modify the effects of nonpharmacological treatments on patient outcomes, including continence, quality of life, and harms?

KQ 2

What are the benefits and harms of pharmacological treatments of UI in women, and how do they compare with each other?

I. How do pharmacological treatments affect UI, UI severity and frequency, and quality of life when compared with no active treatment?
II. What are the harms from pharmacological treatments when compared with no active treatment?
III. What is the comparative effectiveness of pharmacological treatments when compared with each other?
IV. What are the comparative harms from pharmacological treatments when compared with each other?
V. Which patient characteristics, including age, type of UI, severity of UI, baseline diseases that affect UI, adherence to treatment recommendations, and comorbidities, modify the effects of the pharmacological treatments on patient outcomes, including continence, quality of life, and harms?

KQ 3

What are the comparative benefits and harms of nonpharmacological versus pharmacological treatments of UI in women?

I. What is the comparative effectiveness of nonpharmacological treatments when compared with pharmacological treatments?
II. What are the comparative harms of nonpharmacological treatments when compared with pharmacological treatments?
III. Which patient characteristics, including age, type of UI, severity of UI, baseline diseases that affect UI, adherence to treatment recommendations, and comorbidities, modify the relative effectiveness of nonpharmacological and

pharmacological treatments on patient outcomes, including continence, quality of life, and harms?

KQ 4

What are the benefits and harms of combined nonpharmacological and pharmacological treatment of UI in women?

I. How do combined nonpharmacological and pharmacological treatments affect UI, UI severity and frequency, and quality of life when compared with no active treatment?
II. What are the harms from combined nonpharmacological and pharmacological treatments when compared with no active treatment?
III. What is the comparative effectiveness of combined nonpharmacological and pharmacological treatments when compared with nonpharmacological treatment alone?
IV. What is the comparative effectiveness of combined nonpharmacological and pharmacological treatments when compared with pharmacological treatment alone?
V. What is the comparative effectiveness of combined nonpharmacological and pharmacological treatments when compared with other combined nonpharmacological and pharmacological treatments?
VI. What are the comparative harms from combined nonpharmacological and pharmacological treatments when compared with nonpharmacological treatment alone, pharmacological treatment alone, or other combined treatments?
VII. Which patient characteristics, including age, type of UI, severity of UI, baseline diseases that affect UI, adherence to treatment recommendations, and comorbidities, modify the effects of combined nonpharmacological and pharmacological treatments on patient outcomes, including continence, quality of life, and harms?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Populations:

Inclusion

Adult and elderly (as defined by authors) women with symptoms of UI (as defined by authors).

Subpopulations:

I. Women athletes and those engaging in high-impact physical activities
II. Older women (whether “elderly” or just older than a younger analyzed subgroup, as defined by authors)
III. Women in the military or veterans
IV. Racial and ethnic minorities

Exclusion

If >10% of study participants are children or adolescents, men, pregnant women, institutionalized or hospitalized participants, have UI caused by neurological disease or dual fecal and urinary incontinence.

Intervention/Exposure:

Inclusion

Nonpharmacological interventions: Health education about UI; behavioral therapy, including “lifestyle” interventions (e.g., dietary modifications, weight loss, fluid restriction), bladder training; biofeedback; pelvic floor muscle training and other physical therapy; vaginal cones/weights, bladder supports (e.g., Impressa®); therapeutic pessaries; electrical stimulation (e.g., posterior tibial nerve stimulation, sacral neuromodulation, intravaginal electrical stimulation); magnetic stimulation; urethral plugs and patches; urethral bulking, including transurethral or periurethral injections.

Pharmacological interventions: Estrogen preparations (topical estrogen); antimuscarinics (e.g., oxybutynin chloride, trospium chloride, darifenacin, solifenacin succinate, fesoterodine, tolterodine, propiverine); calcium channel blockers (e.g., nimodipine); botulinum toxin injections; TRPV1 antagonists (e.g., resiniferatoxin); antidepressants (e.g., tricyclics, SSRI, SNRI); beta-3 adeno-receptor agonists (e.g., mirabegron).

Combinations of eligible nonpharmacological and pharmacological interventions.

Exclusion
Interventions not available in the United States and surgical treatments.

Comparator:

Inclusion
Other eligible nonpharmacological interventions, other eligible pharmacological interventions, other eligible combination interventions, no active treatment or placebo.

Exclusion
Noneligible interventions, including surgery.

Outcomes:

Inclusion
Measures of UI: Pad tests and other measures of leakage volumes; incontinence counts/frequency (e.g., by diary), including urgency UI counts/frequency and stress UI counts/frequency; physical examination (e.g., cough stress test); complete remission, improvement (partial remission), worsening, no change; subjective bladder control; patient satisfaction with intervention; need to use protection.

Quality of life and related questionnaires: Generic, validated; UI-specific, validated.

Other patient-centered outcomes, based on the findings of the contextual question (what defines a successful outcome).

Adverse events.

Exclusion
Bladder and pelvic tests that do not measure UI specifically or are used for diagnostic purposes (e.g., urodynamic testing, pelvic muscle strength); urination measures that do not measure UI specifically (e.g., total voids [that include nonincontinence voids], catheterization, postvoid residuals, urinary retention, perceived micturition difficulty).

Timing:

Inclusion
Minimum 4 weeks follow up (since the start of treatment).

Exclusion
None.

Settings:

Inclusion
Interventions provided in primary care or specialized clinic or equivalent by any healthcare provider; participants are community-dwelling.

Exclusion
Surgical, institutionalized, or in-hospital settings.
Country setting.

Inclusion

Any geographic area.

Exclusion

None.

Study designs:

Inclusion

For effectiveness outcomes: Randomized controlled trials (RCTs), with no minimum sample size, including pooled individual patient data from RCTs; nonrandomized comparative studies that used strategies to reduce bias (e.g., adjustment, stratification, matching, or propensity scores), N≥50 women per group (N≥100 women total).

For harms outcomes: RCTs, with no minimum sample size; nonrandomized longitudinal comparative studies (regardless of strategies to reduce bias), including registries or large databases, N≥50 women per group (N≥100 women total); single arm longitudinal studies, including registries, large databases, and large case series N≥100 women; case-control studies (where cases are selected based on presence of harm), N≥50 female cases and ≥50 female controls (N≥100 women total).

All outcomes: Published, peer-reviewed articles or unpublished data from the Food and Drug Administration (FDA) or from the Web site ClinicalTrials.gov.

Exclusion

For effectiveness outcomes: Single group, case-control, and case report/series studies; nonrandomized comparative studies with only crude or unadjusted data.

Publication language.

Inclusion

Any.

Exclusion

Unable to read or translate.

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